Fixed Combination Aerosol Foam Calcipotriene 0.005% (Cal) Plus Betamethasone Dipropionate 0.064% (BD) is More Efficacious than Cal or BD Aerosol Foam Alone for Psoriasis Vulgaris

A Randomized, Double-blind, Multicenter, Three-arm, Phase 2 Study

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ABSTRACT

Objective: To evaluate the efficacy of fixed combination aerosol foam calcipotriene 0.005% (Cal) plus betamethasone dipropionate 0.064% (BD). **Design:** Patients were randomized (100:101:101) to receive Cal/BD foam, Cal foam, or BD foam once daily for four weeks. **Setting:** Twenty-eight United States centers. **Participants:** 302 patients (≥18 years) with psoriasis vulgaris (plaque psoriasis; ≥mild disease severity by physician's global assessment). **Measurements:** Treatment success of the body ("clear"/"almost clear" from baseline moderate/severe disease; "clear" from baseline mild disease). Involved scalp treatment success was an additional endpoint. **Results:** Most patients (76%) had moderate psoriasis of the body (66% for scalp). At Week 4, 45 percent of Cal/BD foam patients achieved treatment success, significantly more than Cal foam (14.9%; OR 4.34 [95%CI 2.16, 8.72] $P<0.001$) or BD foam (30.7%; 1.81 [1.00, 3.26] $P=0.047$). Fifty-three percent of Cal/BD foam patients achieved treatment success of the scalp, significantly greater than Cal foam (35.6%; 1.91 [1.09, 3.35] $P=0.021$), but not BD foam (47.5%; 1.24 [0.71, 2.16] $P=0.45$). Mean modified psoriasis area and severity index (population baseline 7.6) improved in all groups, with statistically significant differences in Week 4 Cal/BD foam score (2.37) versus Cal foam (4.39; mean difference –2.03 [–2.63, –1.43] $P<0.001$) and BD foam (3.37; –1.19 [–1.80, –0.59] $P<0.001$). Four (Cal/BD), 10 (Cal), and 8 (BD) adverse drug reactions were reported. **Conclusion:** Cal/BD foam was significantly more effective than Cal foam and BD foam in providing treatment success at Week 4 and effective on involved scalp. Trial registration: NCT01536938. (*J Clin Aesthet Dermatol.* 2016;9(2):34–41.)

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Data from this study have previously been presented as a poster at AAD 2015 and SDEF Hawaii 2015.

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Psoriasis is a chronic, immune-mediated, inflammatory skin condition, affecting between two and four percent of Western populations.[1] Characterized clinically by well-defined, erythematous, scaly skin plaques, severity can range from a few plaques to involving almost the entire body surface.[1–3] Psoriasis has been recognized by the World Health Organization as a painful, debilitating disease,[4] with increased risk of serious comorbidities, such as cardiovascular disease, diabetes mellitus, and psoriatic arthritis.[5,6] The psychosocial impact of psoriasis and its comorbidities can lead to reduced quality of life, contributing a burden to patients and society.[7,8]

Approximately 80 percent of patients have mild-to-moderate disease and the majority of these patients manage their condition with topical therapies.[9] Established first-line topical interventions for psoriasis patients include combination therapy with vitamin D_3 analogues and topical corticosteroids.[10–12] In clinical studies, gel and ointment formulations of calcipotriene 0.005% (Cal) plus betamethasone dipropionate 0.064% (BD) demonstrate superior efficacy and a favorable safety profile compared with Cal or BD alone.[13,14] Notably, Cal/BD treatment once or twice daily for four or eight weeks was associated with significantly greater reductions in psoriasis severity versus Cal or BD ($P<0.05$), as measured by the validated psoriasis area and severity index (PASI) scale, in patients with psoriasis of the body.[15] Moreover, response to Cal/BD was observed as early as 1 to 2 weeks after treatment initiation.[15]

As with any therapeutic intervention, adherence is a key requirement and it is estimated that at least one-third (39–73%) of patients with psoriasis do not adhere to their prescribed medication regimen.[16] Patient perception of the cosmetic acceptability of a treatment vehicle may be a factor in the complex psychology of patient adherence decision making.[17,18] The alcohol-free fixed combination Cal/BD aerosol foam is an innovative formulation that has potential to improve patient management of psoriasis vulgaris. Cal/BD aerosol foam has been developed to be a more cosmetically acceptable alternative to currently available first-line ointment and gel formulations.

The objective of this Phase 2 trial was to investigate the comparative efficacy of Cal/BD aerosol foam versus the active individual components (Cal aerosol foam and BD aerosol foam) in patients with psoriasis vulgaris of the body. Treatment effect on psoriasis of the scalp was also evaluated.

METHODS

Patients. Eligible patients were ≥18 years of age with at least mild severity psoriasis vulgaris of both the body and scalp, according to the physician's global assessment of disease severity (PGA), who were amenable to 90g/wk topical medication and experienced psoriasis for ≥6-month duration. Patients had psoriasis of the trunk and/or limbs involving ≥2% of total body surface area (BSA; excluding psoriasis on the genitals and skin folds), psoriasis of the scalp involving ≥10% of the total scalp area, and total psoriatic involvement of the trunk, limbs, and scalp ≤30% BSA. Patients also had a modified psoriasis area and severity index (mPASI) score of ≥2 on the trunk and/or limbs at baseline, calculated based on the investigator's assessment of the extent and severity of the psoriasis on the trunk, arms, and legs. Patients with guttate, erythrodermic, exfoliative, or pustular psoriasis were excluded, as were those with infectious or inflammatory skin conditions affecting the treatment area, disorders of calcium homeostasis associated with hypercalcemia, severe hepatic disorders, or severe renal insufficiency.

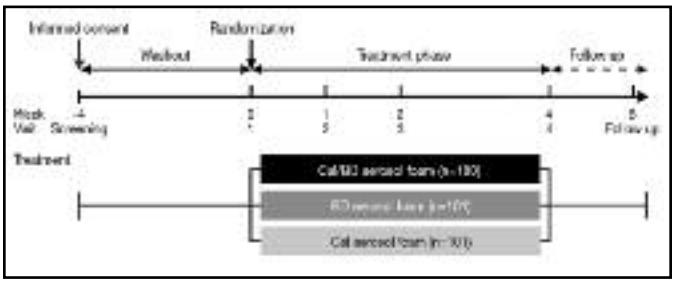

Figure 1. Study design. In the case of an ongoing ADR, a further safety follow-up was performed 2 weeks after the patient's last study visit or until the final outcome was established, whichever occurred first.

ADR=adverse drug reaction; BD=betamethasone dipropionate 0.064%; Cal=calcipotriene 0.005%

Systemic treatment with agents with possible effects on psoriasis was not permitted, including biological therapies, corticosteroids, retinoids, methotrexate, cyclosporine, and other immune suppressants. Washout periods for biologic/systemic treatments were routine. Topical antipsoriatics, psoralen plus ultraviolet light A therapy, or ultraviolet B therapies were discontinued between two and four weeks prior to study treatment. Additionally, patients could not use topical corticosteroids (steroid potency classes 1–5) or vitamin D_3 analogues for psoriasis or skin conditions in non-treatment areas (face, skin folds, and genitals), as well as conditioners, chemical treatments, or medicated shampoos. Concomitant treatment with medication that could affect psoriasis, such as beta-blockers, antimalarials, lithium, and angiotensin-converting enzyme inhibitors, was accepted if the treatment was not initiated, or doses were not changed, during the study.

Study design. This was a randomized, double-blind, three-arm, Phase 2 study conducted at 28 centers in the United States between May 2012 and October 2012 (NCT01536938). Each center enrolled between five and 23 patients who provided written informed consent prior to study entry. The institutional review boards or independent ethics committees of all investigational centers approved the study protocol. The study was performed in accordance with the Declaration of Helsinki and Good Clinical Practice.

The study design comprised a four-week washout phase, if required, followed by a treatment period of up to four weeks (Figure 1). Patients were randomly assigned in a 1:1:1 ratio to one of the following three treatment arms: 1) Cal/BD aerosol foam; 2) Cal aerosol foam; or 3) BD aerosol foam, via a central interactive web response system in accordance

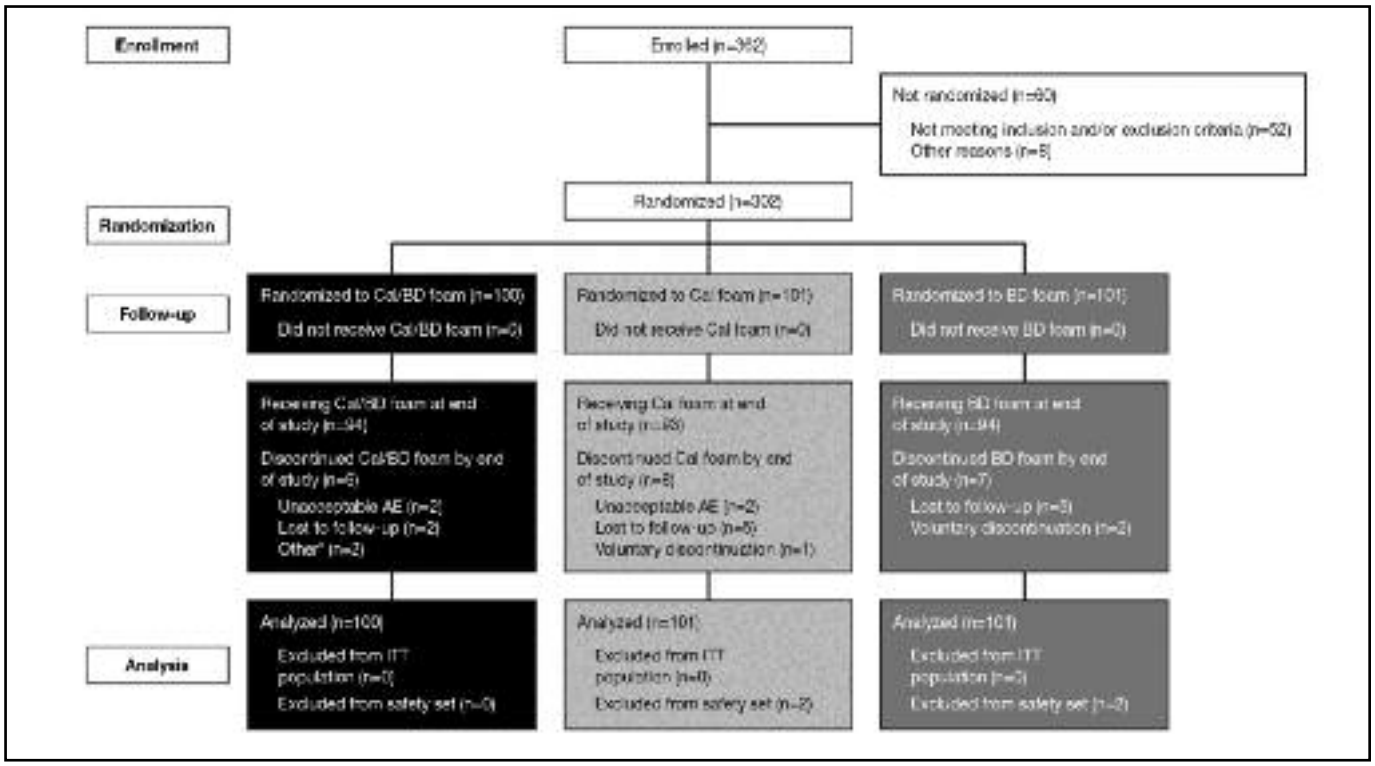

Figure 2. Patient flow CONSORT diagram.
*1 patient was nonadherent to treatment; 1 patient had a visit scheduling error
AE=adverse event; BD=betamethasone dipropionate 0.064%; Cal=calcipotriene 0.005%

with a pre-planned, computer-generated randomization schedule. Randomization was stratified by patient baseline disease severity (mild or at least moderate according to PGA) of the trunk and limbs. Patients applied topical treatment to all psoriasis lesions once daily for four weeks.

Study objectives. The primary objective was to compare the efficacy of Cal/BD aerosol foam with the active individual components in the same vehicle (i.e., vs. Cal aerosol foam and vs. BD aerosol foam) for treatment of psoriasis vulgaris on the trunk and limbs. The primary efficacy endpoint was treatment success of body psoriasis according to PGA at Week 4, defined as "clear" or "almost clear" from baseline for patients with moderate/severe disease and "clear" from baseline for those with mild disease. Secondary endpoints were treatment success of body psoriasis at Week 1 according to PGA and evaluation of safety. Additional efficacy endpoints were achievement of treatment success of the scalp at Weeks 1 and 4, evaluation of mPASI of the body, change in itch score and proportion of patients achieving a 75 or 50-percent reduction in baseline mPASI score (PASI75 and PASI50, respectively) at Week 4. Treatment success on the patient's global assessment of disease severity (PaGA; defined as "clear" or "very mild" disease) was also an additional endpoint.

Assessments. Efficacy endpoints were assessed at baseline and Weeks 1, 2, and 4 of treatment. PGA is a three-item (redness, thickness, and scaling) 5-point severity scale (clear, almost clear, mild, moderate, and severe) that was used as the primary efficacy assessment tool to evaluate global psoriasis on the trunk, limbs, and scalp.[19] For PGA, psoriasis on the trunk and limbs was assessed separately from psoriasis on the scalp. An overall score, taking into account trunk, limbs, and scalp psoriasis assessment was also determined.

The mPASI scoring system was applied in an exploratory capacity to assess the extent and severity of clinical signs of psoriasis (plaque thickness, scaliness, and redness). For a given affected region (scalp, arms, trunk, and legs), the extent of psoriatic involvement was graded from 0 (no involvement) to 6 (90–100% involvement), while severity for each clinical sign was recorded on a scale between 0 (none) and 4 (very severe).[20]

Patient assessment of global psoriasis severity was recorded using the PaGA, which comprises a five-point scale denoting increasing symptom severity and interference with daily life (clear, very mild, mild, moderate, or severe disease). Intensity of itch during the previous 24 hours was reported by the patient using a 100mm visual analogue scale (VAS; 0=none; 100=most severe).

Safety assessments comprised the incidence of adverse events (AEs), adverse drug reactions (ADRs; defined as AEs with a possible/probable causal relationship to study treatment), and change from baseline to Week 4 in laboratory parameters and vital signs. In the case of an ongoing ADR, a further safety follow-up was performed two

TABLE 1. Patient demographics and baseline characteristics (full analysis set)

	CAL/BD AEROSOL FOAM (n=100)	CAL AEROSOL FOAM (n=101)	BD AEROSOL FOAM (n=101)
Age, mean (SD), years	47.4 (14.8)	50.7 (14.7)	49.0 (14.4)
Gender, male, n (%)	53 (53.0)	61 (60.4)	56 (55.4)
Race, n (%)			
Caucasian	93 (93.0)	92 (91.1)	83 (82.2)
Black/African American	6 (6.0)	4 (4.0)	8 (7.9)
Asian	1 (1.0)	3 (3.0)	5 (5.0)
Other*	0	2 (2.0)	5 (5.0)
Duration of psoriasis, mean (SD), years	14.6 (13.8)	18.4 (14.6)	16.2 (13.3)
BSA involved, mean (SD), %	6.7 (4.9)	7.2 (5.6)	7.6 (6.3)
PGA,† n (%)			
Mild	9 (9.0)	13 (12.9)	10 (9.9)
Moderate	77 (77.0)	75 (74.3)	81 (80.2)
Severe	14 (14.0)	13 (12.9)	10 (9.9)
mPASI,† mean (SD)	8.8 (4.6)	8.6 (4.4)	8.1 (4.0)

BSA=body surface area; BD=betamethasone dipropionate 0.064%; Cal=calcipotriene 0.005%; mPASI=modified psoriasis area and severity index; PGA=physician's global assessment of disease severity
***Including American Indian, Native Alaskan, Hawaiian Native or other Pacific Islander, or other**
†Trunk, limbs and scalp

weeks after the patient's last study visit or until the final outcome was established, whichever occurred first. Blood and spot urine samples were collected for laboratory analyses at baseline and study endpoint (Week 4). Laboratory biochemistry and urinalysis parameters included calcium, albumin, and creatinine. Additionally, albumin-corrected serum calcium and urinary calcium:creatinine ratio parameters were calculated.

Statistical analysis. It was calculated that a sample size of 100 in each group would provide 83 percent power to detect a difference between 50 percent of patients having treatment success by PGA for the trunk and limbs in the Cal/BD aerosol foam group and 30 percent of patients having treatment success in the active comparison groups. Efficacy analyses were conducted on the full analysis set (intent-to-treat), which comprised all randomized patients.

The primary and secondary efficacy analyses compared the proportion of patients with treatment success according to PGA at Weeks 4 and 1, respectively, using the Cochran–Mantel–Haenszel test adjusted for study center. For each treatment comparison, an odds ratio (OR; odds of treatment success for Cal/BD aerosol foam relative to the comparator), 95% confidence interval (CI), and *P*-value was calculated. The efficacy of Cal/BD was determined based on a statistically significant effect at the five percent level in favor of combination treatment for both comparisons. Change in mPASI between treatment groups was tested using analysis of covariance including center, treatment, and baseline score in the model. Last observation carried forward analysis was applied to PGA, PaGA, and mPASI scores, when required, to impute missing efficacy data points. Analysis of the additional endpoint for patient-reported itching was performed on observed values. Data from the safety population, comprising all patients who received at least one dose of study treatment and/or had available data on AEs, were summarized descriptively.

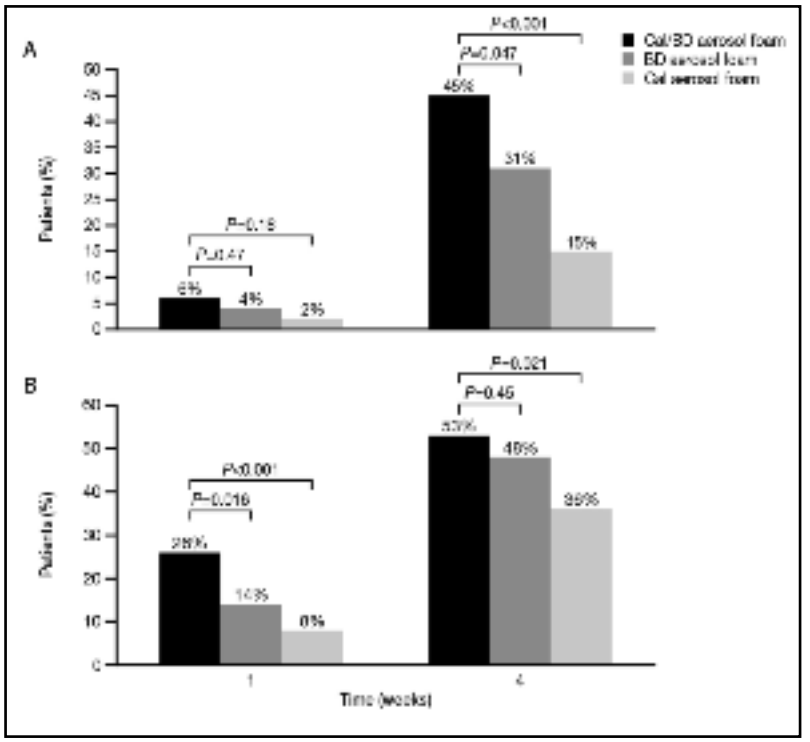

Figure 3. Proportion of patients achieving treatment success according to physician's assessment of the A) body and B) scalp at Week 1 and 4 with Cal/BD, Cal, and BD aerosol foam (full analysis set). Treatment success was defined as "clear" or "almost clear" from baseline for patients with moderate/severe disease and "clear" from baseline for those with mild disease. Missing values were imputed by LOCF; *P*-values were determined using Cochran–Mantel–Haenszel test, adjusting for pooled centers.
BD=betamethasone dipropionate 0.064%; Cal=calcipotriene 0.005%; LOCF=last observation carried forward

RESULTS

Patients. In total, 362 patients were enrolled in the study, 302 of whom were randomized to Cal/BD aerosol foam (n=100), Cal aerosol foam (n=101), or BD aerosol foam (n=101). The majority of patients (93.0%) completed the study, with similar withdrawal rates between the Cal/BD (6.0%), Cal (7.9%), and BD (6.9%) aerosol foam arms (Figure 2). Most patient withdrawals were because of losses to follow-up; two Cal/BD patients (2.0%) and five each (5.0%) in the Cal and BD aerosol foam arms. Within the Cal/BD and Cal aerosol foam treatment groups, two patients (2.0%) in each withdrew due to AEs. Patient demographics and baseline characteristics were similar between treatment groups (Table 1).

Efficacy. ***Investigator assessments.*** Cal/BD aerosol foam provided treatment success of body psoriasis at Week 4 in 45 percent of patients, according to PGA, which was significantly greater than that observed for patients treated with Cal aerosol foam alone (14.9%, OR 4.34; 95% CI 2.16, 8.72; $P<0.001$) or BD aerosol foam alone (30.7%; OR 1.81; 95% CI 1.00, 3.26; $P=0.047$; Figure 3A). At Week 1, more patients treated with Cal/BD aerosol foam achieved treatment success (6.0%) compared with Cal aerosol foam (2.0%) or BD aerosol foam (4.0%) alone, although these differences between groups did not reach statistical significance (Figure 3A). Over the second week of treatment, the proportion of patients with treatment success increased more rapidly in the Cal/BD aerosol foam group than in BD and Cal aerosol foam groups, and remained higher throughout the rest of the treatment period.

Treatment success of the scalp with Cal/BD aerosol foam was significantly greater than with Cal aerosol foam at Week 4 (53.0 vs. 35.6%; OR 1.91; 95% CI 1.09, 3.35; $P=0.021$), but not BD aerosol foam (47.5%; OR 1.24; 95% CI 0.71, 2.16; $P=0.45$; Figure 3B). At Week 1, a significantly higher proportion of patients treated with Cal/BD aerosol foam (26%) achieved treatment success of the scalp compared with patients treated with Cal aerosol foam (7.9%; OR 4.13; 95% CI 1.69, 10.09; $P<0.001$), as well as those who received BD aerosol foam (13.9%; OR 2.48; 95% CI 1.18, 5.22; $P=0.016$; Figure 3B).

PASI. Mean mPASI score for body psoriasis improved in all groups from a population baseline score of 7.6, with statistically significant differences in the Week 4 Cal/BD aerosol foam score (2.37) compared with Cal aerosol foam (4.39; mean difference –2.03; 95% CI –2.63, –1.43; $P<0.001$) and BD aerosol foam alone (3.37; mean difference –1.19; 95% CI –1.80, –0.59; $P<0.001$; Figure 4). The mean percentage reduction in mPASI score at Week 4 was 71 percent for patients treated with Cal/BD aerosol foam compared with 42 percent for Cal aerosol foam and 55 percent for BD aerosol foam alone. At Week 4, PASI75 was achieved by 49, 18, and 34 percent of patients with Cal/BD, Cal, and BD aerosol foam, whereas PASI50 at Week 4 was achieved by 80, 44, and 59 percent, respectively ($P<0.001$ Cal/BD vs. Cal for PASI75; $P\leq0.003$ for PASI50 in both comparisons).

Patient-reported outcomes. Patient-reported PaGA outcomes considered body and scalp psoriasis together. At Week 4, significantly more patients assessed that they had achieved treatment success with Cal/BD aerosol foam (60%) than with Cal aerosol foam (30%; OR 3.74; 95% CI 2.02, 6.91; $P<0.001$) or BD aerosol foam (41%; OR 2.23; 95% CI 1.26, 3.97; $P=0.005$; Figure 5).

Intensity of itch, as assessed by patients (VAS scale), improved for all groups at Week 4, with a mean reduction of 43.4, 30.3, and 44.8 points for Cal/BD, Cal, and BD aerosol foam, respectively. Differences in itch intensity between Cal/BD aerosol foam and comparator groups at Week 4 reached significance versus Cal aerosol foam alone (mean difference: –15.3; 95% CI –21.4, –9.1; $P<0.001$), but not BD aerosol foam (mean difference: –3.2; 95% CI –9.4, 3.0; $P=0.31$). Moreover, significantly greater improvement in itching with Cal/BD aerosol foam versus Cal aerosol foam

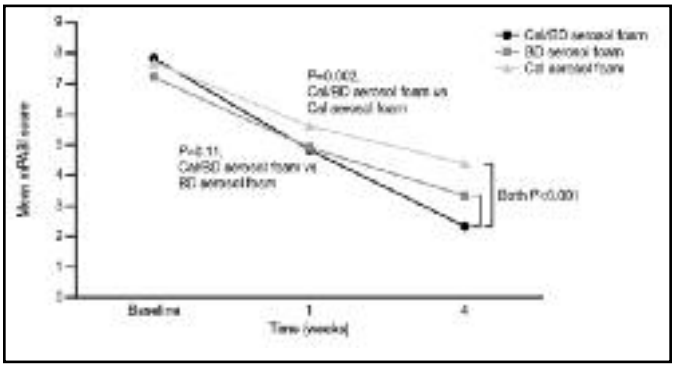

Figure 4. Mean mPASI scores of body at baseline, Week 1 and 4 with Cal/BD, Cal, and BD aerosol foam (full analysis set). Missing values were imputed by LOCF; *P*-values were determined by ANCOVA, adjusting for pooled center and baseline mPASI. ANCOVA=analysis of covariance; BD=betamethasone dipropionate 0.064%; Cal=calcipotriene 0.005%; LOCF=last observation carried forward; mPASI=modified psoriasis area and severity index

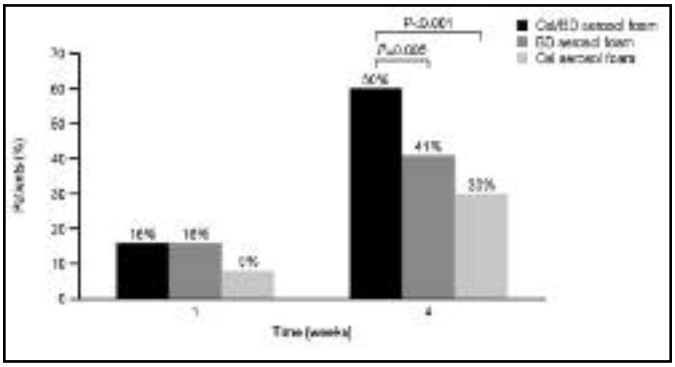

Figure 5. Treatment success according to patient-reported assessment at Week 1 and 4 with Cal/BD, Cal, and BD aerosol foam (full analysis set). Treatment success (by PaGA, considered body and scalp psoriasis together) was defined as "clear" or "very mild" disease. Missing values were imputed by LOCF for Week 4 comparisons; *P*-values were determined using Cochran–Mantel–Haenszel test, adjusting for pooled centers.
BD=betamethasone dipropionate 0.064%; Cal=calcipotriene 0.005%; LOCF=last observation carried forward; PaGA=patient's assessment of disease severity

TABLE 2. Adverse events experienced by more than one patient across all aerosol foam treatment groups

ADVERSE EVENT	CAL/BD AEROSOL FOAM (n=100)	CAL AEROSOL FOAM (n=99)	BD AEROSOL FOAM (n=99)
Medication residue	0	2	3
Application-site pain	1	1	1
Hypersensitivity	1	1	0
Nasopharyngitis	0	1	1
Contusion	1	0	1
Vitamin D decreased	1	0	1
Bronchitis	0	0	2

BD=betamethasone dipropionate 0.064%; Cal=calcipotriene 0.005%

alone was observed at Week 1 (mean difference: –7.4; 95% CI –13.4, –1.4; *P*=0.017).

Safety. The mean weekly amounts of investigational products used throughout this study were 32.9g (standard deviation, 21.6) for Cal/BD aerosol foam, 35.4g (21.7) for Cal aerosol foam, and 35.8g (22.3) for BD aerosol foam.

The overall incidence of patients experiencing AEs was low and similar between the Cal/BD aerosol foam (11 [11%]), Cal aerosol foam (10 [10.1%]) and BD aerosol foam (13 [13.1%]) groups. The majority of events were of mild or moderate intensity. The most commonly experienced AEs were medication residue and application-site pain (Table 2).

Two patients in each of the Cal/BD aerosol foam and Cal aerosol foam groups discontinued as a result of AEs. In the Cal/BD group, these events were irregular menstruation and severe hypersensitivity (urticaria), with the latter event considered possibly related to study drug. Medication residue and contact dermatitis events, which caused discontinuation in one Cal aerosol foam patient each, were both judged as probably related to study treatment. Four, 10, and 8 ADRs were reported with Cal/BD, Cal, and BD aerosol foam, respectively. Within the Cal/BD aerosol foam group, all ADRs (application-site pain, hypersensitivity, alopecia, and buccal mucosal roughening) were single events.

Mean changes from baseline to Week 4 in albumin-corrected serum calcium and urinary calcium:creatinine ratios, as well as vital signs, were small and not considered to be clinically significant for any treatment group. Median albumin-corrected serum calcium levels were 2.3mmol/L in each treatment group at baseline (reference range: 2.15–2.55mmol/L) and median change in these levels were 0.0 mmol/L in each group at Week 4. No patients experienced levels above the normal range, although seven patients had albumin-corrected serum calcium levels lower than the normal range at baseline, and five of these patients achieved normal levels by the end of treatment. Median urinary calcium:creatinine ratios were 2.2, 2.1, and 2.0mmol/g at baseline in the Cal/BD, Cal, and BD aerosol foam groups (normal range 0.225–8.200 female; 0.300–6.100mmol/g male); at Week 4 median change in these values were –0.3, 0.0, and 0.1mmol/g, respectively. Three patients in the Cal aerosol foam group and one patient in the BD aerosol foam group developed urinary calcium:creatinine values above the normal range.

DISCUSSION

This Phase 2, randomized, double-blind study found that Cal/BD aerosol foam was significantly more effective than Cal aerosol foam alone and BD aerosol foam alone in the treatment of psoriasis vulgaris of the body. The main efficacy findings were based on the PGA tool, and these findings were supported by patient-assessed evaluations of efficacy and itch relief.

Cal/BD aerosol foam demonstrated a rapid effect, providing more patients with treatment success (45%) than either Cal aerosol foam or BD aerosol foam alone; a numerical difference in favor of Cal/BD aerosol foam was observed as early as Week 1. The higher rates of treatment success in the Cal/BD aerosol foam group were sustained throughout the study and reached a statistically significant difference by Week 4. Treatment success rates seen here are consistent with those achieved in other efficacy studies of the new aerosol foam formulation.[21,22] Cal/BD aerosol foam also provided more patients with improvements in mPASI at each time point. Although mPASI was evaluated in an exploratory capacity, Cal/BD aerosol foam was significantly more efficacious than both active individual components by Week 4. Mean mPASI in the Cal/BD aerosol foam group was also significantly improved compared with Cal aerosol foam by Week 1. The amount of drug used was numerically lower in the Cal/BD aerosol foam group than the Cal aerosol foam and BD aerosol foam groups.

Cal/BD aerosol foam was also effective in providing treatment success on the involved scalp, with 53 percent of patients achieving treatment success at Week 4, greater than the percentage of patients achieving treatment success of the body. It is interesting to note that whereas Cal/BD aerosol foam achieved superiority over Cal aerosol foam, this threshold was not achieved versus BD, although Cal/BD demonstrated a numeric advantage over BD. Cal/BD aerosol foam did achieve superiority to both Cal and BD aerosol foam at Week 1; however, treatment success events were relatively low at this early time point. Treatment success rates increased in all groups between Weeks 1 and 4.

In this study Cal/BD, Cal, and BD aerosol foam each exhibited good safety profiles. The AE profile of Cal/BD aerosol foam was consistent with the established safety profile of each active ingredient, and that seen in fixed combination preparations of gel and ointment formulations.[15] Combination treatment did not appear to be associated with more treatment-related AEs than the individual component arms. Cal/BD aerosol foam also had minimal impact on calcium homeostasis parameters, which confirms results seen in previous studies specifically designed to evaluate this effect.[23] Limitations of this trial include the lack of a vehicle control group, although a similar Phase 2 study did compare against a non-treatment control.[22]

In conclusion, Cal/BD aerosol foam was significantly more effective than Cal aerosol foam and BD aerosol foam in providing treatment success, with 45 percent of Cal/BD aerosol foam patients achieving treatment success of the body at Week 4. Cal/BD aerosol foam was also effective on the involved scalp, with the majority of patients (53%) achieving treatment success at Week 4. Cal/BD aerosol foam demonstrated a good safety profile and the aerosol foam fixed combination shows promise as a future treatment option for psoriasis vulgaris.

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